

- DRAFT CHLORAMINE-T LABEL CLAIM -- FOR REVIEW ONLY -



Chemical name: Chloramine-T

Original NADA Claim supported by accepted pivotal efficacy data

Potential NADA Claim pending development of additional efficacy data

Species: <u>Salmonids</u> Indication: <u>For the control of</u> <u>mortalities associated with</u>

external flavobacterial infections of gills.1

Dosage Regimen: Apply 12 to 20 milligrams chloramine-T per liter [mg/L; equivalent to parts per million (ppm)] as a static bath in fish culture units for 60 min.

Limitations/comments:

- Treat fish culture units once per day on alternate days three times per epizootic to control mortalities associated with external flavobacterial infections of gills.
- Application of chloramine-T should be preceded by a bioassay with a representative sample of the target population to assess the sensitivity of the target population.
- ¹ Note: Original NADA is contingent on acceptance by CVM of technical guidelines for human food safety, mammalian toxicology, product chemistry, target animal safety, and environmental safety.

Species: All freshwater fish 1

Indication: <u>For the control of mortalities associated with external</u> flavobacterial infections of gills.

Dosage Regimen: Apply 12 to 20 milligrams chloramine-T per liter [mg/L; equivalent to parts per million (ppm)] *in constant flow water supply*² *of fish culture units* or as a static bath in fish culture units for 60 min.

Limitations/comments:

- Treat fish culture units once per day on consecutive³ or alternate days three times per epizootic to control mortalities associated with external flavobacterial infections of gills.
- Application of chloramine-T should be preceded by a bioassay with a representative sample of the target population to assess the sensitivity of the target population.
- ¹ Note: The number of species included in the potential NADA claim is directly related to the number of species included in the supporting INAD efficacy trials. Assumes that pivotal INAD efficacy data for a major cooland warmwater aquaculture species are developed and accepted and supporting INAD efficacy data are developed for additional cool- and warmwater species. UMESC also assumes that CVM will not require additional environmental safety data with the addition of this disease indication.
- ² Note: Use in continuous flow water supply of fish culture units would require the development of data that show the ability to maintain the minimum nominal treatment concentration and that there is an acceptable environmental assessment for this use.
- ³ Note: Use to treat on consecutive days would require the development of additional target animal safety data in salmonids. Target animal safety data supporting consecutive daily treatments at 20 mg/L have been developed for cool- and warmwater fish.

Limitations and Cautions that apply to all uses:

- Follow NPDES or state discharge regulations for discharge of chloramine-T treatment water.
- Flow to the culture unit must be sufficient to rapidly flush chloramine-T from the culture unit after treatment.
- Avoid feeding fish before or during exposure. Before treatment, remove dead fish and clean rearing units to be treated.
- Consider using aeration to help disperse the chemical and to ensure adequate oxygen levels.

Withdrawal time in days:

For Ingredient: Chloramine-T

There is no established withdrawal time for this ingredient. However, UMESC expects that the withdrawal time will be less than 21 days for freshwater-reared salmonids based on human food safety data.

Tolerance in food animals:
For Ingredient: Chloramine-T
CFR Tolerance Paragraph Number: N/A
The marker residue for Chloramine-T is paratoluenesulfonamide (p-TSA). The proposed
(working) tolerance for the marker residue is 1 mg/kg
in the edible fillet.



